Coconino County Environmental Services Code, Rules and Regulations of the Coconino County Public Health Services District

CHAPTER 20 BODY ART CODE

Section 20-1	GENERAL PROVISIONS
REG. 20-1-1	Legal Authority
REG. 20-1-2	Scope
REG. 20-1-3	Definitions
REG. 20-1-4	Prohibitions
REG. 20-1-5	Exemptions
Section 20-2	LICENSES, PERMITS, AND CERTIFICATES
REG. 20-2-1	License Requirements
REG. 20-2-2	Temporary Demonstration Permit Requirements
REG. 20-2-3	Issuance of License
REG. 20-2-4	Plan Review Requirements
REG. 20-2-5	Time Frames
Section 20-3	INSPECTIONS, VARIANCES AND RESPONSIBILITIES
REG. 20-3-1	Inspections
REG. 20-3-2	Modifications and Variances
REG. 20-3-3	Responsibilities of the License Holder
REG. 20-3-4	Responsibilities of the Regulatory Authority
Section 20-4	Operator-Certificates
REG. 20-4-1	Operator Certificates
REG. 20-4-2	Operator Trainee Certificates
REG. 20-4-3	Temporary Establishment Permit/Operator Certificates
Section 20-5	Operator Requirements and Records
REG. 20-5-1	Body Art Operator/Technician Requirements and Professional Standards
REG. 20-5-2	Jewelry Requirements and Professional Standards
REG. 20-5-3	Public Notification Requirements
REG. 20-5-4	Client Records
REG. 20-5-5	Records Retention
Section 20-6	Sanitation
REG. 20-6-1	Preparation and Care of the Body Art Area
REG. 20-6-2	Sanitation and Sterilization Procedures
REG. 20-6-3	Requirements for Single-Use Items
Section 20-7	Ear Piercing
REG. 20-7-1	Specifications and Requirements
Section 20-8	Facilities
	Requirements for Premises
Section 20-9	Enforcement

REG. 20-9-1 Enforcement: License Suspension or Revocation

Appendix A: Universal Precautions Appendix B: Disclosure Statement

Appendix C: CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities,

2008

RULES AND REGULATIONS FOR BODY ART Chapter 20

SEC.20-1 GENERAL PROVISIONS

REG.20-1-1 Legal Authority

The regulations in this Chapter are adopted pursuant to the authority granted by the Coconino County Board of Directors which is authorized in A.R.S. 11-251(17) to adopt provisions necessary to preserve the health of the county, in A.R.S. 11-251(31) to make and enforce all local, police, sanitary and other regulations not in conflict with the general laws and in 13-3721 making certain body art practices unlawful.

REG.20-1-2 Scope

The purpose of these regulations is to regulate Body Art and Body Art Establishments in a manner that will protect the public health, safety and welfare; prevent spread of disease; and prevent the creation of a nuisance within Coconino County.

REG.20-1-3 Definitions

- A. <u>Aftercare</u> means written instructions given to the client, specific to the body art procedure(s) rendered, about caring for the body art and surrounding area. These instructions will include information about when to seek medical treatment, if necessary.
- B. <u>Antiseptic</u> means an agent that destroys disease-causing micro-organisms on human skin or mucosa.
- C. APP means the Association of Professional Piercers.
- D. ASTM means the American Society for Testing and Materials.
- E. <u>Blood borne pathogens</u> means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
- F. <u>Body art</u> means the practice of physical body adornment by permitted establishments and operators using, but not limited to, the following techniques: body piercing, tattooing, cosmetic tattooing, permanent skin coloring, branding, and scarification. This definition does not include practices that are considered medical procedures by a state medical board, such as implants under the skin, which shall not be performed in a body art establishment, practices that are noninvasive forms of painting by use of dyes or inks, or practices considered by the State Board of Cosmetology to be Aesthetics, Cosmetology or Nail Technology.
- G. <u>Body art establishment</u> means any licensed place or premise, whether public or private, temporary or permanent, in nature or location, where the practices of body art, whether or not for profit, are performed.

H. Body piercing means puncturing or penetration of the skin of a person with pre-

sterilized single-use needles and the insertion of pre-sterilized jewelry or other adornment thereto in the opening, including puncturing the outer perimeter or lobe of the ear with a pre-sterilized single-use needle. Under no circumstances shall stud-and-clasp ear piercing guns or systems be used anywhere on the body, except on the outer lobe of the ear. All stud-and-clasp ear piercing guns and systems must be capable of being sterilized.

- I. <u>Certification</u> means an approved County training program including Body Art certification. Certification cannot be used as a health license or permit.
- J. <u>Cleaning area</u> means the area in a body art establishment used in the sterilization, sanitization or other cleaning of instruments or other equipment used for body art activity.
- K. Communicable disease means any disease transmitted from one person or animal to another directly, by contact with excreta or other discharges from the body; or indirectly, via substances or inanimate objects, such as water or contaminated needles; or via vectors such as flies, ticks, or other insects. Kinds of communicable diseases include those caused by bacteria, fungi, parasites, and viruses.
- L. <u>Contaminated waste</u> means any liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; sharps and any wastes containing blood and other potentially infectious materials, as defined in 29 Ordinance of Federal Regulations Part 1910.1030 (latest edition), known as "Occupational Exposure to Bloodborne Pathogens."
- M. Cosmetic tattooing see TATTOOING.
- N. <u>Critical item</u> means a provision of this Chapter that, if in noncompliance, is more likely than other violations to contribute to contamination, illness, or environmental health hazards. "Critical item" is an item that is denoted in this Chapter as (critical).
- O. <u>Department</u> means the Arizona Department of Health Services.
- P. <u>Disinfection</u> means the destruction or inactivation or removal of disease-causing micro-organisms on inanimate objects or surfaces, thereby rendering these objects safe for use or handling.
- Q. <u>Ear piercing</u> means the puncturing of the outer perimeter or lobe of the ear with a pre-sterilized single-use needle following manufacturer's instructions. All ear piercing studs and clasp guns or systems must be capable of being sterilized.
- R. <u>Equipment</u> means all machinery, including fixtures, containers, vessels, tools, devices, implements, furniture, display and storage areas, sinks, and all other apparatus and appurtenances used in connection with the operation of a body art establishment.
- S. <u>Event-related shelf-life</u> is based on the principle that specific events, not time, are responsible for sterile products that are sterilized in an approved manner at a

licensed Body Art establishment from becoming contaminated. The shelf life of a

packaged sterile item is event-related and depends on:

- a. The quality of the packaging material
- b. The storage conditions
- c. Conditions during transport
- d. The amount of handling prior to use
- T. <u>Hand sink</u> means a lavatory equipped with hot and cold running water under pressure, used solely for washing hands, arms, or other portions of the body.
- U. <u>Hot water</u> means water that attains and maintains a temperature of at least 100 degrees F.
- V. <u>ISO</u> means the International Organization for Standardization.
- W. Implantation means to permanently insert or fix an object subcutaneously.
- X. <u>Instrument sink</u> means a lavatory used solely for scrubbing instruments and utensils used in body art.
- Y. <u>Instrument storage area</u> means the area in a body art establishment used in the storage of instruments, linens, and other items used in any body art activity.
- Z. <u>Instruments used for body art</u> means hand pieces, needles, needle bars, and other instruments that may come in contact with a client's body or may be exposed to bodily fluids during body art procedures.
 - AA. <u>Invasive</u> means entry into the body either by incision or insertion of an instrument into or through the skin or mucosa, or by any other means intended to puncture, break, or compromise the skin or mucosa.
 - BB. <u>Jewelry</u> means any personal ornament inserted into a newly pierced area, which must be made of surgical implant-grade stainless steel; solid 14k or 18k white or yellow gold, or raw titanium, which has been properly sterilized prior to use.
 - CC. <u>Liquid chemical germicide</u> means a disinfectant or sterilant registered with the U.S. Environmental Protection Agency.
 - DD. <u>Operator/technician</u> means any person who controls, operates, manages, conducts, or practices body art activities at a body art establishment and who is responsible for compliance with these regulations, whether actually performing body art activities or not. The term includes technicians who work under the operator and perform body art activities.
 - EE. Permanent skin coloring see TATTOOING
 - FF. <u>Permit / License</u> mean the documentation issued by the Regulatory Authority that authorizes a person to operate a Body Art establishment.
 - GG. <u>Physician</u> means a person licensed by the State of Arizona to practice medicine in all its branches and may include other areas such as dentistry, osteopathy, or acupuncture, depending on the rules and regulations particular to that state.
 - HH. <u>Procedure area</u> means the area in a body art establishment which contains the workstation, cleaning area, and instrument storage area.
 - II. <u>Procedure surface</u> means any surface of an inanimate object that contacts the client's unclothed body during a body art procedure, skin preparation of the

area adjacent to and including the body art procedure, or any associated work

area which may require sanitizing.

- JJ. <u>Public water system</u> has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.
- KK. <u>Regulatory authority</u> means the department, local health department, or public health services district operating under the delegation of authority from the Department.
- LL. <u>Sanitization procedure</u> means a process of reducing the numbers of micro-organisms on cleaned surfaces and equipment to a safe level as judged by public health standards and which has been approved by the District.
- MM. <u>Sharps</u> mean any objects (sterile or contaminated) that may purposefully or accidentally cut or penetrate the skin or mucosa, including, but not limited to, pre-sterilized, single-use needles; scalpel blades; and razor blades.
- NN. <u>Sharps container</u> means a puncture-resistant, leak-proof container that can be closed for handling, storage, transportation, and disposal and that is labeled with the international bio-hazard symbol.
- OO. <u>Single use</u> means products or items that are intended for one-time, one-person use and are disposed of after use on each client, including, but not limited to, cotton swabs or balls, tissues or paper products, paper or plastic cups, gauze and sanitary coverings, razors, piercing needles, scalpel blades, stencils, ink cups, and protective gloves. These items are neither designed nor intended to be cleaned, disinfected, or sterilized for reuse.
- PP. <u>Sterilization</u> means destruction of all forms of microbial life, including highly resistant bacterial spores.
- QQ. <u>Suspension</u> means the act of hanging the body from large hooks for the purpose of spiritualistic ritual or a test of endurance.
- RR. <u>Tattooing</u> means any method of placing ink or other pigment into or under the skin or mucosa by the aid of needles or any other instrument used to puncture the skin, resulting in permanent coloration of the skin or mucosa. This term includes all forms of cosmetic tattooing and permanent skin coloring such as eyeliner, eyebrows, lip liner, full lip color, re-pigmentation or camouflage.
- SS. <u>Temporary body art establishment</u> means any place or premise operating at a fixed location where an operator performs body art procedures for no more than seven (7) days consecutively in conjunction with a single event or celebration.
- TT. <u>Universal precautions</u> means a set of guidelines and controls, published by the Centers for Disease Control and Prevention (CDC), as "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers" in Morbidity and Mortality Weekly Report (MM WR), June 23, 1989, Vol.38, No. S-6, and as "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures", in MMWR, July 12, 1991, Vol.40, No. RR-8. This method of infection control requires the employer and the employee to assume that all

human blood and specified human body fluids are infectious for HIV; HBV;

and other blood pathogens. Precautions include hand-washing; gloving; personal protective equipment; injury prevention; and proper handling and disposal of needles, other sharp instruments, and blood- and body fluid-contaminated products.

UU. <u>Workstation</u> means the area in a body art establishment used exclusively in and during the conduct of body art upon a client.

REG.20-1-4 Prohibitions

A. The following acts are prohibited:

- 1. It is prohibited to perform body art on any body part of a person under the age of 18 without the written consent and physical presence of the parent or legal guardian of such minor. This consent shall be given in person to the body artist or responsible person at the facility by the parent or legal guardian prior to the time application of the body art is to commence. Photographic identification of the parent or legal guardian is required. Proof of parentage by birth certificate, proof of guardianship by court order of guardianship, or a notarized document signed by the parent or legal guardian attesting to the parent's/legal guardian's relationship to the client and consent to the conduct of the contemplated body art activity upon the client shall be given to the operator prior to the procedure. (Critical)
- 2. It is prohibited to tattoo or pierce the body of another person to use a needle or any substance that will leave color under the skin more than once or to use a needle that is not sterilized with equipment used by state licensed medical facilities pursuant to A.R.S. 36, Ch. 4. (Critical)
- 3. It is prohibited to use a stud-and-clasp piercing gun or system more than once, unless the gun or system is a pre-sterilized single-use stud-and-clasp ear-piercing system or is capable of being disinfected and is actually disinfected after being used. If in the course of the piercing procedure, the gun or system is exposed to blood, it must be autoclaved. (Critical)¹
- 4. It is prohibited to administer anesthesia during the course of any procedure involving the branding, scarifying, tattooing, implanting, mutilating or piercing of the body of another person without a license issued pursuant to A.R.S. title 32. (Critical)
- 5. It is prohibited to engage in the business of tattooing, branding, scarifying, implanting, mutilating or body piercing out of a home or an impermanent structure, including a tent, trailer, trunk or other impermanent structure. (Critical)
- 6. It is prohibited to perform body art on a person who, in the opinion of the operator, is inebriated or appears to be under the influence of alcohol or drugs. (Critical)
- 7. It is prohibited to own, operate, or solicit business as a body art establishment or operator without first obtaining all necessary licenses,

permits, certifications, and approvals from the District, unless specifically

- exempted by this Chapter. (Critical)
- 8. It is prohibited to obtain or attempt to obtain any body art establishment license or operator certification by means of fraud, misrepresentation, or concealment. (Critical)
- 9. It is prohibited to perform invasive procedures such as suspensions or implantations that do not meet the intent of this Chapter. (Critical)

REG.20-1-5 Exemptions

This Regulation does not apply to the following:

Physicians licensed by the State of Arizona, who perform either independent of or in connection with body art procedures as part of patient's treatment, are exempt from these regulations.

SECTION 20-2 LICENSES, PERMITS, AND CERTIFICATES REG.20-2-1 License Requirements

- A. Body art establishments must apply for a license from the regulatory authority. Only persons who comply with all the requirements of this Chapter shall be entitled to receive and retain such licenses.
- B. A license shall be issued in the name of the owner, manager, or operator of a body art establishment for a specific location and shall be non-transferable.
- C. A license issued by the regulatory authority is valid for a period of one (1) year from the date of issuance. The license may be suspended or revoked after an opportunity for a hearing by the regulatory authority if the license holder violates any of the terms or provisions of this Chapter.
- D. Licensing Requirements: To apply for a license to operate a Body Art Establishment, the following forms and fees must be submitted.
 - 1. Building Division "Certificate of Occupancy"
 - 2. Body Art Establishment license application
 - 3. Required fee for a Body Art Establishment license as approved by the Coconino County Public Health Services District Board of Directors. The current approved fee schedule for the Health District is available at District offices as well as available at our website.
 - 4. The license shall not be issued or renewed until the license applicant/holder demonstrates that the sterilization process used is capable of attaining sterilization by monthly spore destruction tests and by chemical test strips. The sterilization process to destroy spores must be received by the District before the permit is issued or renewed. These test records shall be retained by the operator for a period of three (3) years and made available to the District upon request.
- E. The holder of a body art establishment license must only hire operators who have complied with the operator certification requirements of this Chapter. (Critical)
- F. Prior to the issuance of any license, an inspection of the premises and all installations thereon shall be made by the regulatory authority. Inspections shall be made as frequently as deemed necessary to verify compliance with these

REG.20-2-2 Temporary Demonstration Permit Requirements

- A. A temporary permit may be issued by the District for guest artists or for educational, trade show or product demonstration purposes only. The permit is good for no more than seven (7) calendar days.
- B. A person who wishes to obtain a temporary demonstration permit must submit the request in writing for review by the District, at least thirty days prior to the event. The request should specify:
 - 1. The purpose for which the permit is requested;
 - 2. The period of time during which the permit is needed (not to exceed 7 calendar days per event), without re-application;
 - 3. The fulfillment of operator requirements as specified in Reg. 20-2-9;
 - 4. The location where the temporary demonstration permit will be used.
- C. The applicant's demonstration project must be contained in a completely enclosed, non-mobile facility (e.g., inside a permanent building).
- D. If the demonstration is to occur outside of a permitted body art establishment, compliance with all of the requirements of this Chapter includes but is not limited to the following:
 - 1. Readily accessible located hand-washing facilities with germicidal liquid soap, paper towels in a dispenser and hot and cold water under adequate pressure shall be provided. Drainage in accordance with local plumbing ordinances is to be provided. Tuberculocidal single- use hand wipes, approved by the District, to augment the hand washing requirements of this section must be available in each booth/ cubicle.
 - 2. A minimum of 80 square feet of floor space shall be provided; There shall be at least 100 foot candles of light at the level where the body art procedure is being performed;
 - 3. Facilities shall properly sterilize instruments- and evidence of a spore test performed on sterilization equipment 30 days or less prior to the date of the event, must be provided; or only single-use, prepackaged, sterilized equipment obtained from commercial suppliers or manufacturers will be allowed; and
 - 4. Ability to properly clean and sanitize the area used for body art procedures is required.
- E. If the facility where the temporary demonstration permit is needed is not a permitted body art establishment, the facility must be inspected by the District and a permit issued prior to the performance of any body art procedures.
- F. Temporary demonstration permits issued under the provisions of this Chapter may be suspended by the District for failure of the holder to comply with the requirements of this Chapter.
- G. All establishment permits, operator certifications, and the disclosure notice must be readily seen by clients. (Critical)

REG.20-2-3 Issuance of License

- A. A body art establishment license issued by the regulatory authority shall bear the following information:
 - 1. The name of the body art establishment;
 - 2. The street address of the body art establishment;
 - 3. The full name of the license holder;
 - 4. The mailing address of the license holder; and
 - 5. A unique identification number assigned by the regulatory authority.

REG.20-2-4 Plan Review Requirements

- A. A license applicant or license holder shall submit to the regulatory authority properly prepared plans and specifications for review and approval before:
 - 2. The construction of a body art establishment;
 - 3. The conversion of an existing structure for use as a body art establishment;
 - 4. The remodeling of a body art establishment if the regulatory authority determines that plans and specifications are necessary to ensure compliance with this Chapter.
- B. To be considered Administratively Complete, the following forms, information and fees must be submitted for a Body Art Establishment Approval to Construct:
 - 1. Documentation of:
 - a. Planning and Zoning approval for this proposed establishment
 - b. Approved public water system
 - c. Approved wastewater facilities
 - 2. A complete and signed Body Art Plan Review Worksheet and plans containing detailed information on structural requirements, Operational requirements, Operator requirements, equipment schedule, site plan, floor plan, finish schedule, lighting schedule, mechanical schematics, construction materials, and sanitary requirements;
 - 3.Submit a floor plan of the facility. In the drawing include where hand sinks, instrument & autoclave area, janitorial sink, operator areas, waiting area, plumbing & wastewater lines, etc. will be positioned. Information on ventilation, lighting, doors and windows must be verified in the plan review process. "Pre-submittal" meetings can be scheduled to discuss requirements, or any other questions pertaining to plan review.
 - 4. Equipment types, manufacturers, model numbers, locations, dimensions, performance capabilities, and installation specifications;
 - 5. Evidence that procedures ensure compliance with the requirements of this Chapter developed or are being developed;
 - 6. Procedures for operating a body art establishment;
 - 7. Other information for the proposed construction, conversion, or modification, for constructing a body art establishment.

- 8. Required fee for a Body Art Plan Review as approved by the Coconino County Public Health Services District Board of Directors. The current approved fee schedule for the Health District is available at District offices as well as available at our website.
- C. Preoperational inspections shall be conducted by the regulatory authority to verify that the body art establishment is constructed and equipped in accordance with the approved plans and modifications, has established standard operating procedures, and is in compliance with law and this Chapter.

REG.20-2-5 Time-Frames

- A. This section applies to the District which has been delegated by the Department to comply with ARS 11-1605 through 11-1606.
- B. The regulatory authority approval time-frames described in ARS 11-1601 are set forth in Table 1. The applicant or license holder and the regulatory authority may agree in writing to extend the substantive review and the overall time-frame but an extension may not exceed 25% of the overall time-frame.
- C. The administrative completeness review time-frame begins on the date that the regulatory authority receives an application or request for approval.
 - 1. The regulatory authority shall mail or send an electronic notice of administrative completeness or deficiencies to the applicant or license holder within the time-frame.
 - A notice of deficiencies shall list each deficiency and the information and documentation needed to complete the application or request for approval.
 - b. If the regulatory authority issues a notice of deficiencies within the administrative completeness review time-frame, the administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice is issued until the date that the regulatory authority receives the missing information from the applicant or license holder.
 - c. If within 180 days the applicant or license holder fails to submit all of the information and documents listed in the notice of deficiencies, the regulatory authority shall consider the application or request for approval withdrawn.
 - 2. If the regulatory authority issues a license or other approval to the applicant or license holder during the administrative completeness review time-frame, the regulatory authority shall not issue a separate written notice of administrative completeness.
- D. The substantive review time-frame begins on the administrative completeness notice date.
 - 1. The regulatory authority shall mail or send electronically written notification of approval or denial of the application or other request for

approval to the applicant or license holder within the substantive review time-frame.

- 2. As part of the substantive review for a facility license, the regulatory authority may complete an inspection that may require more than 1 visit to the facility.
- 3. During the substantive review time-frame, the regulatory authority may make 1 comprehensive written request for additional information, unless the regulatory authority and the applicant or license holder have agreed in writing to allow the regulatory authority to submit supplemental requests for information.
- E. The regulatory authority shall issue a license or approval unless:
 - 1. The regulatory authority determines that the body art establishment license application or the body art establishment does not satisfy all of the requirements of this Chapter;
 - 2. For a request for a variance, the regulatory authority determines that the request fails to demonstrate that the variance will not result in a health hazard or nuisance;
 - 3. For a request for approval of plans and specifications, the regulatory authority determines that the plans and specifications do not satisfy all of the requirements of this Chapter; and
 - 4. For a request for approval of a quality assurance program, the regulatory authority determines that the quality assurance program does not satisfy all requirements of this Chapter.
 - a. If the regulatory authority disapproves an application or request for approval, the regulatory authority shall send the applicant or license holder a written notice of disapproval setting forth the reasons and all other information required by ARS 11-1606.
- F. For the purpose of computing time-frames, the day of the act, event, or default from which the designated period of time begins, shall not be included. Intermediate Saturdays, Sundays, and legal holidays shall be included in the computation. The last day of the period computed shall be included unless it is a Saturday, Sunday, or legal holiday, in which event, the period runs until the end of the next day that is not a Saturday, Sunday, or legal holiday.

Table 1. Time-frames (in days)

Type of Approval	Statutory	Overall	Administrative	Substantive
	Authority	Time-	Completeness	Review Time-
		frame	Review Time-frame	frame
Body Art	ARS 36-	60	30	30
Establishment	136(H)(4)			
License				
Approval of Request	ARS 36-	90	30	60
for Variance	136(H)(4)			
Approval of Plans	ARS 36-	90	30	60
and Specifications	136(H)(4)			
Approval of Quality	ARS 36-	90	30	60
Assurance Program	136(H)(4)			

SECTION 20-3 INSPECTIONS, VARIANCES AND RESPONSIBILITIES REG.20-3-1 Inspections

- A. Frequency The regulatory authority or his/her representatives shall inspect any body art establishment as often as may be necessary to assure compliance with these regulations, but not less than two inspections per year. A copy of the inspection report shall be furnished to the owner, lessee, or operator of the body art establishment, indicating the degree of compliance or non-compliance with provisions to these regulations. Failure to correct any discrepancy noted within the time limit specified shall be cause for denial, revocation, or suspension of the license to operate. A temporary Body Art facility shall be inspected as often as necessary to assure compliance with these regulations, but not less once per the 7 consecutive day duration of the permit.
- B. Reasonable Time After Due Notice After the District presents official credentials and provides notice of purpose and intent to conduct an inspection, the person in charge shall allow the regulatory authority to determine if the licensed facility is in compliance with this Chapter. The person in charge shall allow access to the facility, allow an inspection, and provide information and records specified in this Chapter and to which the regulatory authority is entitled according to law. The District to which the duty to comply with ARS 41-1009 has been delegated by the Department, shall comply with ARS 41-1009 and 11-1603 when performing inspections.
- C. Specifying Time Frame for Corrections The regulatory authority shall specify the violation correction time frame on the inspection report.
- D. Issuing Report and Obtaining Acknowledgment of Receipt At the conclusion of the inspection, the regulatory authority shall provide a copy of the completed inspection report to the license holder or person in charge, and request a signed acknowledgment of receipt according to law.

- E. Refusal to Sign Acknowledgment The regulatory authority shall:
 - 1. Inform a PERSON who declines to sign an acknowledgment of receipt of inspectional findings as specified in this Chapter that:
 - a. An acknowledgment of receipt is not an agreement with findings,
 - b. Refusal to sign an acknowledgment of receipt will not affect the PERMIT/LICENSE HOLDER'S obligation to correct the violations noted in the inspection report within the time frames specified, and
 - c. A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the District historical record for the BODY ART ESTABLISHMENT; and
 - 2. Make a final request that the PERSON IN CHARGE sign an acknowledgment receipt of inspectional findings.
- F. Public Information The District shall treat the inspection report as a public document and shall make it available for disclosure to a PERSON who requests it as provided by law.
- G. Ceasing Operations and Reporting A permit/license holder shall immediately discontinue operations and notify the regulatory authority if an IMMINENT HEALTH HAZARD may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, SEWAGE backup, misuse of POISONOUS OR TOXIC MATERIALS, onset of an apparent communicable disease outbreak, gross unsanitary occurrence or condition, or other circumstance that may endanger public health. A license holder need not discontinue operations in an area of an establishment that is unaffected by the IMMINENT HEALTH HAZARD.
- H. Resumption of Operations If operations are discontinued the license holder shall obtain approval from the regulatory authority before resuming operations.
- I. Time Frame for Correction of Critical (Critical) Violations
 - 1. The license holder shall correct critical items by a date and time agreed to or specified by the regulatory authority but no later than 10 calendar days after the inspection. The regulatory authority may approve a compliance schedule that extends beyond the time limits of this section if a written schedule of compliance is submitted and no health HAZARD exists or will result from allowing an extended schedule for compliance. The shall not provide a license holder an opportunity to correct critical violations after the date of inspection if the District determines that the deficiencies are:
 - a. Committed intentionally;
 - b. Not correctable within a reasonable time:
 - c. Evidence of a pattern of noncompliance; or
 - d. A risk to any person; the public health, safety, or welfare, or the environment.

- 2. If the District allows the license holder an opportunity to correct violations or deviations after the date of inspection, the District shall inspect the body art establishment after the deadline for correction. If the District
 - determines that the violations or deviations have not been corrected, the District may take enforcement action authorized by law based upon those violations or deviations.
- 3. A decision made by the District under this section of the Chapter is not an appealable agency action as defined by ARS 11-1603 G and ARS 41-1092.
- J. Verification and Documentation of Correction At the time of inspection, if a correction of a critical violation or deviation is observed, the regulatory authority shall enter the violation and information about the corrective action on the inspection report.
- K. Time Frame for Correction of Non-Critical Violations
 - 1. The license holder shall correct non-critical violations by a date and time agreed to or specified by the regulatory authority but no later than 90 calendar days after the inspection.
 - 2. The regulatory authority may approve a compliance schedule that extends beyond the time limits specified in this Section if a written schedule of compliance is submitted by the license holder and no health hazard exists or will result from allowing an extended compliance schedule.

REG.20-3-2 Modifications and Variances

- A. The regulatory authority may grant a variance by modifying or waiving the requirements of this Chapter if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the variance. If a variance is granted, the regulatory authority shall retain the information in its records for the body art establishment.
- B. Documentation of Proposed Variance and Justification
 - 1. Before a variance is approved, the following shall be provided to the District:
 - a. A statement of the proposed variance citing relevant regulation numbers of this Chapter;
 - b. The rationale and analysis for how potential public health hazards and nuisances will be alternatively addressed by the proposal.
- C. Conformance with Approved Procedures
 - 1. If the regulatory authority grants a variance, the license or permit holder shall:
 - b. Comply with the plans and procedures that are submitted and approved;
 - c. Provide to the regulatory authority, upon request, records that demonstrate the following are routinely employed and maintained;
 - i. Verification of the effectiveness of the operation or process; and

ii. Necessary corrective actions if there is failure.

REG.20-3-3 Responsibilities of the License Holder

- A. Upon acceptance and retention of the issued license, the license holder shall:
 - 1. Post the license in the facility that is conspicuous to consumers; (Critical)
 - 2. Comply with the provisions of this Chapter including the conditions of a granted variance and approved plans;
 - 3. Immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist;
 - 4. Allow representatives of the regulatory authority access to the body art establishment;
 - 5. Replace existing facilities and equipment with those that comply with this Chapter if:
 - a. Facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which facilities and equipment were accepted;
 - b. Required because of a change of ownership; or
 - c. The facilities and equipment are replaced in the normal course of operation;
 - 6. Comply with the regulatory time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the regulatory authority in regard to the licensed facility or in response to community emergencies.
 - 7. Accept notices issued and served by the regulatory authority according to law; and
 - 8. Be subject to the administrative, civil, injunctive, and criminal remedies authorized by law for failure to comply with this Chapter or a directive given by the regulatory authority, including time frames for corrective actions.

REG.20-3-4 Responsibilities of the Regulatory Authority

- A. The regulatory authority shall provide a copy of this Chapter to the license holder when a license is first issued so the license holder is notified of compliance requirements.
- B. Failure to provide the information in this section does not prevent the regulatory authority from taking authorized action or seeking remedies if the license holder fails to comply with this Chapter or an order, warning, or directive from the regulatory authority.

SEC.20-4 OPERATOR CERTIFICATES

REG.20-4-1 Operator Certificates

A. No person shall practice body art procedures without first obtaining an operator certificate from the District. The District shall charge a reasonable fee for such certificates, as set forth in the fee schedule adopted by the Board of Directors.

(Critical)

B. The operator certificate shall be valid from the date of issuance and shall automatically expire in three (3) years from the date of issuance unless revoked

sooner by the District in accordance with this Chapter.

- C. Application for an operator certificate shall include:
 - 1. Name:
 - 2. Social Security and driver's license numbers;
 - 3. Date of birth;
 - 4. Sex;
 - 5. Residence address;
 - 6. Mailing address;
 - 7. Phone number;
 - 8. Place(s) of employment as an operator;
 - 9. Training and/ or experience;
 - 10. Proof of attendance at a blood borne pathogen training program (or equivalent), given or approved by the District;
 - 11. Proof of completion of the Hepatitis B vaccination series, or a written declination on the form provided by the District.
- D. Operator Certificates may be issued by the District, after satisfaction of the following requirements:
 - 1. Applicant is free of communicable diseases that may be transmitted to a patron;
 - a. Unless the applicant declines in writing on a form provided by the District, before any Operator Certification may be issued or renewed, the applicant must be immunized against Hepatitis B. In the event that such information is not obtained and filed in a timely fashion by any applicant, the Operator Certification may be suspended or revoked in accordance with the procedures set forth in these Regulations.
 - b. The applicant must begin the Hepatitis B vaccination series prior to being issued an operator certification unless the applicant has previously received the complete Hepatitis B vaccination series and can provide documentation to the District; antibody testing has revealed that the applicant is immune; or the vaccine is contraindicated for medical reasons; or the applicant has declined in writing on a form provided by the District.
 - 2. Applicant is a minimum of eighteen (18) years of age;
 - 3. Applicant has a minimum of six (6) months experience or training as a body art operator in a duly-licensed establishment in Arizona or another state with similar licensing standards.
 - 4. Applicant has obtained a score of at least eighty (80) percent on an examination of basic sanitation knowledge, pertaining to body art, which will be administered by the District.
- E. No operator certificate shall be issued unless following reasonable investigation

by the District, the body art operator has demonstrated compliance with the provisions of this section and all other provisions of this Chapter.

- F. All operator certificates shall be conditioned upon continued compliance with the
- provisions of this section as well as all applicable provisions of this Chapter. G. All operator certificates shall be posted in a prominent and conspicuous area where they may be readily observed by clients. (Critical)
- H. Probationary operator certificates may be issued by the District to operators who have met all the requirements of this Chapter except their prior experience has not been acquired while operating in a duly licensed establishment in Arizona or another state with similar licensing standards to those in Coconino County. Probationary certificates shall be valid for six (6) months. Upon completion of all requirements of this Chapter, a regular operator certificate will be issued for no additional fee.

REG.20-4-2 Operator Trainee Certificates

- A. A person who is training to become a licensed operator must obtain an operator-trainee certificate from the District. The District shall charge a reasonable fee for such certificates, as set forth in the fee schedule adopted by the Board of Directors. (Critical)
- B. The operator-trainee certificate is valid from the date of issuance and shall automatically expire in one (1) year from the date of issuance unless revoked sooner by the District in accordance with this Chapter.
- C. Application for an operator-trainee certificate shall include the information listed in this Chapter.
- D. Operator-trainee certificates may be issued by the District after satisfaction of the following requirements:
 - 1. Applicant is free of communicable diseases that may be transmitted to a patron;
 - a. Before any Operator-trainee certification may be issued, the applicant must be immunized against Hepatitis B unless the applicant declines in writing on a form approved by the District.
 - b. The operator-trainee must begin the Hepatitis B vaccination series prior to being issued an operator certification unless: he has previously received the complete Hepatitis B vaccination series and can provide documentation to the District; antibody testing has revealed that the operator is immune; the vaccine is contraindicated for medical reasons; or if the applicant has declined in writing on a form approved by the District.
 - 2. Applicant must be at least eighteen (18) years of age.
 - 3. Applicant will work under the direct supervision of an operator licensed in Coconino County by the District.
 - 4. Applicant has obtained a score of at least eighty (80%) on an examination of basic sanitation knowledge pertaining to body art, which will be administered by the District.

- E. All operator-trainee certificates shall be conditioned on continued compliance with the provisions of this section as well as all applicable provisions of this Chapter.
- F. All operator-trainee certificates shall be posted in a prominent and conspicuous area where they may be readily observed by the clients. (Critical)

REG.20-4-3 Temporary Establishment Permit / Operator Certificates

- A. Temporary establishment permits and, when required, temporary operator permits may be issued for body art services provided outside of the physical site of a certified facility for the purposes of product demonstration, industry trade shows or education, or for a guest artist demonstrating body art technique at a permitted establishment.
 - 1. Temporary operator certificates and/ or establishment permits will not be issued unless:
 - a. The applicant furnishes proof of compliance with Reg. 20-2-1 and Reg. 20-2-7 relating to operators' permits and certifications;
 - b. The applicant is currently affiliated with a fixed location or permanent facility which, where applicable, is permitted by the appropriate state and/ or local jurisdiction;
 - c. The temporary site complies with this Chapter;
 - d. A complete Temporary Body Art Application for permit is submitted; and
 - e. Required fee for a Temporary Body Art Establishment permit as approved by the Coconino County Public Health Services District Board of Directors. The current approved fee schedule for the Health District is available at District offices as well as available at our website.
 - 2. In lieu of attendance at an annual blood borne pathogens training program given by the District within the past year as specified in this regulation, the applicant may furnish proof of attendance at equivalent training which is acceptable to the District.
 - 3. Temporary permits and certificates expire after seven (7) consecutive days or the conclusion of the special event, whichever is less.
 - 4. Temporary operator certificates and/ or establishment permits will not be issued unless the applicant has paid a reasonable fee as set by the District.
 - 5. Temporary establishment permits/ operator certificates shall not be transferable from one place or person to another.
 - 6. Temporary establishment permits/ operator certificates shall be posted in a prominent and conspicuous area where they may be readily seen by clients.

SEC.20-5 OPERATOR REQUIRMEMENTS AND RECORDS REG.20-5-1 Body Art Operator /Technician Requirements and Professional Standards

A. It shall be unlawful for any person to own or operate a body art establishment or

to perform body art procedures unless such procedures are performed in a body art establishment with a current license from the District. (Critical)

B. The following information shall be kept on file on the premises of a body art

establishment and available for inspection by the District: (Critical)

- 1. Employee information
 - a. Full names and exact duties;
 - b. Date of birth;
 - c. Gender:
 - d. Home address;
 - e. Home/work phone numbers;
 - f. Identification photos of all body art operator/technicians; and
 - g. Documentation of Hepatitis B immunizations.
- 2. Establishment information to be maintained for Each Body Art Operator and Technician.
 - a. Establishment name;
 - b. Hours of operation; and
 - c. Owner's name and address.
- 3. A complete description of all body art procedures performed.
- 4. A record of the types of all instruments and body jewelry, all sharps, and all inks used for any and all body art procedures, including names of manufacturers and serial or lot numbers, if applicable. Invoices or orders shall satisfy this requirement.
- 5. A copy of these regulations.
- C. The following information must be prominently displayed in the body art establishment and shall not be altered or defaced in any manner:
 - 1. Body Art Establishment License (Critical)
 - 2. Body Art Operator Certificate for each operator/technician (Critical)
 - 3. Disclosure Statement (Appendix B) (Critical)
- D. The body art operator/technician must be a minimum of 18 years of age. (Critical)
- E. Smoking, eating, or drinking alcoholic beverages, being under the influence of drugs or alcohol by either the operator or client is prohibited in the body art workstation, cleaning area and instrument storage areas. (Critical)
- F. Operators/technicians shall refuse service to any person who, based on reasonable observation and inquiry, is under the influence of alcohol or drugs. (Critical)
- G. The operator/technician shall maintain a high degree of personal cleanliness, conform to hygienic practices, and wear clean clothes when performing body art procedures. Before performing body art procedures, operators/technicians must thoroughly wash their hands in hot running water with dispensed liquid soap, then rinse hands and dry with dispensed disposable paper towels. This shall be done as often as necessary to remove contaminants. (Critical)
- H. In performing body art procedures, the operator shall wear disposable medical gloves. Gloves must be changed if they become contaminated by contact with any non-clean surfaces or objects or by contact with a third person or when interruptions in the procedure occur to prevent cross-contamination. The gloves

shall be discarded, at a minimum, after the completion of each procedure on an individual client, and hands shall be washed before the next set of gloves is donned. Under no circumstances shall a single pair of gloves be used on more

than one person. The use of disposable medical gloves does not preclude or substitute for hand-washing procedures as part of a good personnel hygiene program. (Critical)

- I. If, while performing a body art procedure, the operator's/technician's glove is pierced, torn, or otherwise contaminated, the procedure delineated in this Chapter shall be repeated immediately. The contaminated gloves shall be immediately discarded, and the hands washed thoroughly before a fresh pair of gloves is applied. Any item or instrument used for body art that is contaminated during the procedure shall be discarded and replaced immediately with a new disposable item or a new sterilized instrument or item before the procedure resumes. (Critical)
- J. Contaminated waste, as defined in this Chapter, that may release liquid blood or body fluids when compressed or may release dried blood or body fluids when handled must be placed in an approved container marked with the international bio-hazard symbol. It must then be disposed of by a waste hauler approved by the District or, at a minimum, in compliance with 29 CFR Part 1910.1030, "Occupational Exposure to Blood borne Pathogens". Sharps ready for disposal shall be disposed of in approved sharps containers. Sharps containers must be replaced routinely and not be allowed to overfill. Contaminated waste that does not release liquid blood or body fluids when compressed or does not release dried blood or body fluids when handled may be placed in a covered receptacle and disposed of through normal, approved disposal methods. (Critical)
- K. No person shall perform any body art procedure including ear piercing, upon a person under the age of 18 years without the physical presence, consent, and proper identification of a parent, legal custodial parent, or legal guardian. Nothing in this section is intended to require an operator to perform any body art procedure on a person under 18 years of age with parental or guardian consent. (Critical)
 - 1. Age of <u>ALL</u> patrons must be verified via picture identification and documented prior to the procedure being performed. (Critical)
 - 2. Picture identification of <u>ALL</u> patrons for verification of age must be photocopied and kept with the patron's paperwork. (Critical)
- L. No person who is not licensed pursuant to A.R.S. Title 32 shall administer anesthesia during the course of any procedure involving the branding, scarifying, tattooing, implanting, mutilating, or piercing of the body of another person. (Critical)
- M. Any skin or mucosa surface to receive a body art procedure shall be free of rash or any visible infection.
- N. The skin of the operator/technician shall be free of rash or infection. No person or operator affected with boils, infected wounds, open sores, abrasions, keloids, weeping dermatological lesions or acute respiratory infection (which may include, but is not limited to, the common cold, influenza, pneumonia, and tuberculosis)

shall work in any area of a body art establishment in any capacity in which there is a likelihood that that person could contaminate body art equipment, supplies, or working surfaces with body substances or pathogenic organisms. (Critical)

- O. Operators with Hepatitis B or other blood borne communicable diseases are prohibited from performing body art procedures. (Critical)
- P. Proof shall be provided upon request of the District that all operators/technicians have either completed or were offered and declined, in writing, the hepatitis B vaccination series. This offering shall be included as a pre-employment requirement. A copy of the written declination shall be kept in the District files. (Critical)

REG.20-5-2 Jewelry Requirements and Professional Standards

- A. Jewelry inserted into a newly pierced area, must be made of the following materials, in accordance with the Association of Professional Piercers (APP):
 - 1. Steel that is ASTM F-138 compliant or ISO 5832-1 compliant;
 - 2. Steel that is ISO 10993-6, 10993-10, and/or 10993-11 compliant (EEC Nickel Directive compliant);
 - 3. Titanium (Ti6A14V ELI) that is ASTM F136 compliant or ISO 5832-3 compliant;
 - 4. Titanium that is ASTM F-67 compliant;
 - 5. Solid 14 karat or higher nickel-free white or yellow gold;
 - 6. Solid nickel-free platinum alloy;
 - 7. Niobium (Nb);
 - 8. Fused quartz glass, lead-free borosilicate or lead-free soda-lime glass;
 - 9. Polymers including:
 - a. Tygon® Medical Surgical Tubing S-50HL or S-54HL;
 - b. Polytetrafluoroethylene (PTFE) that is ASTM F754-00 compliant; and
 - c. Any plastic material that is ISO 10993-10 and/or 10993-11 compliant and/or meets the United States Pharmacopeia (USP) Class VI material classification.
 - 10. All threaded or press-fit jewelry must have internal tapping (no threads on posts); and
 - 11. For body jewelry purposes, surfaces and ends must be smooth, free of nicks, scratches, burrs, polishing compounds and metals must have a consistent mirror finish.

REG.20-5-3 Public Notification Requirements

- A. Verbal and written public educational information, approved by the District, shall be required to be given to all clients which shall include:
 - 1. Notice that the body art should be considered permanent and removable only by a surgical procedure which may leave permanent scarring and disfigurement; and
 - 2. Instructions, approved by the District, for the aftercare of the body art

procedure site. The written instructions shall advise the client to consult a physician at the first sign of infection or unusual or abnormal swelling and shall contain the name, address, phone number and email address of the

establishment.

- B. These documents shall be signed and dated by both parties, with a copy given to the client and the operator retaining the original with all other required records.
- C. All establishments shall prominently display a Disclosure Statement, provided by the District, which advises the public of the risks and possible consequences of body art services. The facility permit holder shall also post in public view the name, address and phone number of the District that has jurisdiction over this program and the procedure for filing a complaint. The Disclosure Statement and the Notice for Filing a Complaint shall be included in the establishment License Application Packet.
- D. All infections, complications, illnesses or diseases resulting from any body art procedure that become known to the operator shall be reported to the District by the operator within 24 hours. (Critical)

REG.20-5-4 Client Records

- A. So that the operator/technician can properly evaluate the client's medical condition for receiving a body art procedure and not violate the client's rights or confidential medical information, the operator or technician shall ask for the information as follows:
 - 1. In order for us to assist you in the healing of your body art procedure, we ask that you disclose if you have or have had any of the following conditions:
 - a. Diabetes;
 - b. History of hemophilia (bleeding);
 - c. History of skin diseases, skin lesions, or skin sensitivities to soaps, Disinfectants, etc.;
 - d. History of allergies or adverse reactions to pigments, dyes, or other skin sensitivities:
 - e. History of epilepsy, seizures, fainting, or narcolepsy;
 - f. History of jaundice or Hepatitis within twelve (12) months preceding the date of the operation;
 - g. Use of medications such as anticoagulants, which thin the blood and/ or interfere with blood clotting.
- B. The operator/technician should ask the client to sign a Release Form confirming that the above information was obtained or that the operator technician attempted to obtain the information but was refused by the client. The client should be asked to disclose any other information that would aid the operator/technician in evaluating the client's body art healing process.
- C. If the client discloses having within the past twelve (12) months a history of jaundice or Hepatitis, the procedure may not be performed. (Critical)
- D. Each operator and each establishment in which the operator is located shall keep

records of all body art procedures administered, including date, time, identification and location of the body art procedure(s) performed, and operator's name. All client records shall be confidential and be retained as a hard copy or

electronically for a minimum of three (3) years and made available to the District upon notification.

E. Nothing in this section shall be construed to require the operator to perform a body art procedure upon a client.

REG.20-5-5 Records Retention

- A. The body art establishment shall keep a record of all persons who have had body art procedures performed. The record shall include the name, date of birth, and address of the client, the date of the procedure, the name of the operator who performed the procedure(s), type and location of procedure performed, and printed name and written signature of client, and, if the client is a minor, proof of parental or guardian presence and consent, including photo identification of the parent or guardian, name of parent or legal guardian, proof of parentage or legal guardianship through a copy of a birth certificate or court order of guardianship respectively, or a notarized document signed by the parent or legal guardian attesting to the parent's/legal guardian's relationship to the client and consent to the conduct of the contemplated body art activity upon the client. Such records shall be retained as a hard copy or electronically for a minimum of three (3) years and shall be available to the District upon request. The District and the body art establishment shall keep such records confidential. (Critical)
- B. If a licensee, an employee of the licensee or any other person questions or has reason to question that the person ordering, purchasing, attempting to purchase or otherwise procuring or attempting to procure a body art procedure is a minor (under the age of 18 years), the licensee, employee of the licensee or other person shall do all of the following: (Critical)
 - 1. Demand identification from the person;
 - 2. Examine the identification to determine that the identification reasonably appears to be a valid, unaltered identification that has not been defaced;
 - 3. Examine the photograph in the identification and determine that the person reasonably appears to be the same person in the identification;
 - 4. Determine that the date of birth in the identification indicates the person is not a minor; and
 - 5. Copy the individual's identification and the copy shall be retained as a hard copy or electronically for a minimum of three (3) years and shall be available to the District upon request.

SECTION 20-6 SANITATION

REG.20-6-1 Preparation and Care of the Body Art Area

- A. All procedure surfaces of a body art establishment shall be sanitized before and after each body art procedure.
- B. Before a body art procedure is performed, the immediate skin area and the areas of

skin surrounding where the body art procedure is to be placed shall be washed with a germicidal soap and water, and cleansed with a 70% isopropyl alcohol or another antiseptic approved by the District. If shaving is necessary, single-use

disposable razors or safety razors with single-service blades shall be used. Blades shall be discarded after each use, and reusable holders shall be autoclaved after use. Following shaving, the skin and surrounding area shall be washed with a bactericidal soap solution. The washing pad shall be discarded after a single use. (Critical)

- C. If linens or single use disposable paper products are used for any purpose, the following shall apply:
 - 1. Clean linens shall be used for each patron; a common towel is prohibited. (Critical)
 - 2. Clean linens, tissues or single-use paper products shall be stored in a clean, enclosed storage area until needed for immediate use. (Critical)
 - 3. Used linens shall be stored in a closed or covered container until laundered. (Critical)
 - 4. Soiled linens may be laundered in a washing machine with laundry detergent and chlorine bleach or by a regular commercial laundry service. (Critical)
- D. In the event of blood flow, all products used to check the flow of blood or to absorb blood shall be single use and disposed of immediately after use in appropriate covered containers, unless the disposal products meet the definition of biomedical waste (see definition). (Critical)

REG. 20-6-2 Sanitation and Sterilization Procedures

- A. All non-single-use, non-disposable instruments used for body art shall be cleaned thoroughly after each use by scrubbing with a germicidal soap or disinfectant solution and hot water in an instrument sink to remove blood and tissue residue, followed by cleaning in an ultrasonic unit also operated in accordance with manufacturer's instructions. (Critical)
- B. After being cleaned, all non-disposable instruments used for body art shall be packed individually in peel-packs and subsequently sterilized. All peel-packs shall contain either a sterilizer indicator or internal temperature indicator. Sterilized peel-packs must be dated with an expiration date not to exceed thirty (30) days, or an event-related shelf-life practice may be used if sterilized packages are handled using aseptic technique to prevent contamination in accordance with the Centers for Disease Control and Prevention (see Appendix C, CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008). Event-related shelf-life only applies to sterilized packages that are properly sterilized at a licensed body art establishment. However, event-related shelf-life shall not apply to commercially sterilized packages: All expirations dates shall be adhered to. Aseptic technique for an event-related shelf-life includes all of the following: Sterile packages must be stored in a clean and dry washable container with a lid or approved location;

- 1. Sterile packages must be stored at least 8 inches from floor surfaces;
- 2. Sterile packages must be stored at least 5 inches from a ceiling or at least 18 inches from a sprinkler head;
- 3. Sterile packages must be stored at least two inches from an outside wall; and
- 4. Sterile packages cannot be stored in a rest room, utility room, or under sewer or water lines. If a sterile package has presence of tears, cracks, holes, broken seals, evidence of moisture, evidence of poor barrier quality of packaging material, dropped on a floor surface, or presence of dust or soil in the environment or on a package then the item must be immediately re-sterilized. (Critical)

When using an event-related shelf-life sterilized package, use the oldest dated package first.

- C. All cleaned, non-disposable instruments used for body art shall be sterilized in a steam or chemical autoclave. The sterilizer shall be used, cleaned, and maintained according to manufacturer's instruction. A copy of the manufacturer's recommended procedures for the operation of the sterilization unit must be available for inspection by the District. Sterile equipment may not be used if the package has been breached or after the expiration date without first repackaging and re-sterilizing. When a seal is broken on bulk items, the individual items must be re-sterilized before use. Sterilizers shall be located away from work stations or areas frequented by the public. (Critical)
- D. Each holder of a permit to operate a body art establishment shall demonstrate that the sterilizer used is capable of attaining sterilization by monthly spore destruction tests. These tests shall be verified through an independent laboratory. In addition, if a chemical autoclave is used, the permit holder shall demonstrate its use to the District upon request and shall keep a log of disposal dates of chemicals, manner of disposal, and dates of each cleaning. The permit shall not be issued or renewed until documentation of the sterilizer's ability to destroy spores and record logs are reviewed by the District. These test records shall be retained by the operator for a period of three (3) years and made available to the District upon request. (Critical)
- E. After sterilization, the instruments used for tattooing/body piercing shall be stored in a pre-disinfected cabinet or other tightly covered container reserved for the storage of such instruments.
- F. All instruments used for tattooing/body piercing shall remain stored in sterile packages until just prior to the performance of a body art procedure. When assembling instruments used for body art procedures, the operator shall wear disposable medical gloves and use medically recognized techniques to ensure that the instruments and gloves are not contaminated. (Critical)
- G. All inks, dyes, pigments, needles, and equipment shall be commercially manufactured and approved for performing body art procedures and shall be used according to manufacturer's instructions. The mixing of approved inks, dyes, or pigments or their dilution with water from a public water system is acceptable. Immediately before a tattoo is applied, the quantity of the dye to be used shall be

transferred from the dye bottle and placed into single use paper or plastic cups or caps. Upon completion of the tattoo, these single use cups or caps and their contents shall be discarded. (Critical)

REG.20-6-3 Requirements for Single-Use Items

- A. Single-use items shall not be used on more than one client for any reason. After use, all single-use needles, razors, and other sharps shall be immediately disposed of in approved sharps containers, appropriately labeled with the international biohazard symbol (Critical)
- B. All products applied to the skin, including body art stencils, shall be single use and disposable. Products used in application of stencils shall be used and maintained according to the manufacturers instructions. Products used in the application of stencils shall be dispensed and applied on the area to be tattooed with sterile gauze or in a manner to prevent contamination of the original container and its contents. The gauze shall be used only once and then discarded. (Critical)

SEC.20-7 EAR PIERCING

REG.20-7-1 Specifications and Requirements

- A. This section of the Chapter refers to body art establishments that ONLY pierce the ear with a pre-sterilized single-use stud-and-clasp ear-piercing system consistent with the manufacturer's instructions and applicable U.S. Food and Drug Administration requirements.
- B. Body art establishments that only pierce the ear with a pre-sterilized single-use stud-and-clasp ear-piercing system shall comply with ALL regulations of this Chapter except Operator Certification requirements and Operator Trainee Certification requirements.
- C. Body art establishments that only pierce the ear with a pre-sterilized single-use stud-and-clasp ear-piercing system must:
 - 1. Obtain an ear piercing operator certification form, from the District for each operator who provides ear piercing. Ear piercing operator certification shall automatically expire in 3 years from the date of issuance unless revoked sooner by the District in accordance with Section 6.
 - 2. Obtain and provide proof of attendance at an annual blood borne pathogen training program (or equivalent), given or approved by the District for each operator who provides ear piercing;
 - 3. Obtain and provide proof of completion of the Hepatitis B vaccination series, or a written declination on the form provided by the District for each operator who provides ear piercing;
 - a. The operator must begin the Hepatitis B vaccination series prior to performing ear piercing unless he/she has previously received the complete Hepatitis B vaccination series and can provide documentation to the District; antibody testing has revealed that the operator is immune; or the vaccine is contraindicated for medical reasons; or the operator has declined in writing on a form

provided by the District.

- 4. Obtain and provide proof of age for each operator who provides ear piercing. Operator must be a minimum of eighteen (18) years of age.
- D. All operator blood borne pathogen training certifications shall be posted in a prominent and conspicuous area where they may be readily observed by clients. (Critical)
- E. A pre-sterilized single-use stud-and-clasp ear-piercing system can only be used on ears and no other body parts.
- F. Jewelry inserted into a newly pierced area, must comply with the jewelry requirements cited in this Chapter, and properly sterilized prior to use.

SEC.20-8 FACILITIES

REG.20-8-1 Requirements for Premises

- A. Body art establishments applying after adoption of this Chapter shall submit a scale drawing and floor plan of the proposed establishment for a plan review by the District, as part of the Permit Application process. The District shall charge a reasonable fee for this review.
- B. Every workstation, instrument storage area, toilet room, cleaning area and any area in a body art establishment other than the customer waiting area or office, shall be constructed as follows so as to provide a durable smooth, nonabsorbent and washable surface:
 - 1. Floors-constructed of commercially rated continuous sheet vinyl, smooth sealed cement, ceramic tile, or other similar approved materials;
 - 2. Walls-covered with a semi-gloss or gloss enamel paint, or constructed of fiberglass reinforced panel (FRP), or ceramic tile or other similar materials approved by the District; and
 - 3. Ceiling-covered with semi-gloss or gloss enamel paint, or approved acoustical paneling.
 - 4. All such walls and ceilings shall be light-colored. For purposes of this chapter light-colored shall mean a light reflectance value of 70 percent or greater.
 - 5. All walls, floors, and ceilings shall be maintained in a clean condition.
 - 6. All procedure surfaces, including client chairs/benches, shall be of such construction as to be easily cleaned and sanitized after each client.
- C. All body art establishments shall be completely separated by solid partitions or by walls extending from floor to ceiling, from any room used for human habitation, any food establishment or room where food is prepared, any hair salon, or any other such activity that may cause potential contamination of work surfaces. Retail sales shall be separated from the procedures area, instrument cleaning and instrument storage areas. (Critical)
- D. Effective measures shall be taken by the body art operator to protect against entrance into the establishment and against the breeding or presence on the premises of insects, vermin, and rodents. Insects, vermin, and rodents shall not be present in any part of the establishment, its appurtenances, or appertaining

premises. (Critical)

- 1. Doors opening to the outside shall be tight fitting, self closing and insect and rodent proof.
- 2. Windows capable of being opened shall be effectively screened against entrance of insects with 16 mesh to 25.4 mm (16 mesh to 1 inch) screens or smaller.
- E. There shall be a minimum of 45 square feet of floor space for each operator in the establishment. Each establishment shall have an area that may be screened from public view for clients requesting privacy. Multiple body art stations shall be separated by dividers, curtains, or partitions, at a minimum. (Critical)
- F. The establishment shall be well-ventilated and provided with an artificial light source equivalent to at least 20 foot candles 3 feet off the floor, except that at least 100 foot candles shall be provided at the level where the body art procedure is being performed, and where instruments and sharps are assembled.
- G. No animals of any kind shall be allowed in a body art establishment except service animals used by persons with disabilities (e.g., Seeing Eye dogs). Fish aquariums shall be allowed in waiting rooms and non-procedural areas. (Critical)
- H. A separate, readily accessible hand sink with hot and cold running water, under pressure, preferably equipped with wrist- or foot-operated controls and supplied with dispensed liquid soap, and dispensed disposable paper towels shall be readily accessible within the body art establishment. One hand sink shall serve no more than two workstations within the same room if the hand sink is conveniently located and easily accessible for both workstations. A workstation in a separate room or area shall include a hand sink. (Critical)
- I. A separate, readily accessible instrument sink with hot and cold running water, under pressure, shall be readily accessible within the body art establishment. The instrument sink shall NOT be located in a toilet room, utility room, or procedure area. (Critical)
- J. There shall be at least one toilet facility provided in accordance with the Uniform Plumbing Ordinance. Handwashing sinks with hot and cold running water, dispensed liquid soaps and dispensed disposable paper towels shall be located in each toilet facility. (Critical)
- K. At least one janitorial service sink shall be required for establishments.
- L. At least one covered waste receptacle shall be provided in each operator area and each toilet room. Receptacles in the operator area shall be emptied daily, and solid waste shall be removed from the premises at least weekly. All refuse containers shall be emptied daily, lidded, cleanable, and kept clean.
- M. A sealable, rigid (puncture-proof) Sharps© container, appropriately labeled with the international biohazard symbol, that is strong enough to protect the operator, patrons and others from accidental cuts or puncture wounds must be provided for disposal of sharp objects that come in contact with blood and/or body fluids. (Critical)
- N. An autoclave (steam or chemical) sterilizer registered and listed with the Federal Food and Drug Administration, used, cleaned and maintained according to the

> manufacturer's instructions must be at the establishment at all times. In the event the establishment's autoclave is out for repair, another autoclave must be available for use. Sterilizers must be kept clean, in good working order and operated in a

- clean area. Chemicals used for chemical autoclave shall be stored and disposed of in accordance with applicable local, state and federal regulations.(*Critical*)
- O. All instruments and supplies shall be stored in clean, dry, and covered containers.
- P. Reusable cloth items shall be mechanically washed with detergent and bleach and dried after each use. The cloth items shall be stored in a dry, clean environment until used. (Critical)

SEC.20-9 ENFORCEMENT

REG.20-9-1 Enforcement: License, Permit and Certificate Suspension or Revocation

- A. Violation of A.R.S. §13-3721 (incorporated herein as Reg. 20-1-4A1 through Reg. 20-1-4A5 and A8) is a class 6 felony. Violation of any other provision of this Chapter is a class 1 misdemeanor and/or may be subject to civil enforcement action.
- B. Ceasing Operations and Reporting —A PERMIT OR LICENSE HOLDER shall immediately discontinue operations and notify the REGULATORY AUTHORITY if an IMMINENT HEALTH HAZARD may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, SEWAGE backup, misuse of POISONOUS OR TOXIC MATERIALS, onset of an apparent communicable disease outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health. A PERMIT OR LICENSE HOLDER need not discontinue operations in an area of an establishment that is unaffected by the IMMINENT HEALTH HAZARD.
- C. If the District has reasonable cause to suspect that a communicable disease is or may be transmitted by an operator, by use of unapproved or malfunctioning equipment, or by unsanitary or unsafe conditions that may adversely affect the health of the public, upon written notice to the owner or operator, the District may do any or all of the following:
 - 1. Issue an order excluding any or all operators from the permitted body art establishment who are responsible, or reasonably appear responsible, for the transmission of a communicable disease until the District determines there is no further risk to public health.
 - 2. Issue an order to immediately suspend the license or permit of the establishment until the District determines there is no further risk to the public health. Such an order shall state the cause for the action.
- D. Cease and Desist and Abatement of a Public Nuisance: If the regulatory authority has reasonable cause to believe that the licensed facility is creating or maintaining a nuisance, the regulatory authority shall order the license holder to cease and desist such activity and to abate the nuisance as follows:

- 1. The regulatory authority shall serve a written cease and desist and abatement order requiring the license or permit holder to cease and desist such activity and to remove the nuisance within 24 hours of receipt at the license or permit holder's expense. The order shall contain the following:
 - a. A reference to the statute or rule that is alleged to have been violated or on which the order is based,
 - b. A description of the license holder's right to request a hearing, and
 - c. A description of the license holder's right to request an informal settlement conference.
- 2. The regulatory authority shall serve the order and any subsequent notices by personal delivery or certified mail, return receipt requested to the license or permit holder's or other party's last address on record or by any other reasonable method.
- 3. The license or permit holder or other party whose rights were determined by the order may obtain a hearing to appeal with the regulatory authority within 30 days after receiving the order. The license or permit holder or other party shall serve the notice of appeal to the regulatory authority office by personal delivery, certified mail, or return receipt requested or by any other reasonable method.
- 4. If a notice of appeal is timely filed, the regulatory authority shall set a hearing which will be conducted in accordance with the Hearing Officer rules for conducting hearings as set out in Chapter 3 of this Code.
- 5. If no written notice of appeal is timely filed, the order shall become final without further proceedings.
- 6. The regulatory authority shall inspect the licensed or permitted facility 24 hours after the order was delivered to determine whether the license holder has complied. If the regulatory authority determines upon inspection that the license or permit holder has not ceased the activity and abated the nuisance, the regulatory authority shall cause the nuisance to be removed regardless of whether the license or permit holder is appealing the order.
- 7. If the license or permit holder fails or refuses to comply after a hearing has upheld the order or after the time to appeal the order has expired, the regulatory authority may file an action against the license holder in the superior court of the county in which the violation occurred, requesting that a permanent injunction be issued to restrain the license or permit holder from engaging in further violations as described in the order.

E. Suspension or Revocation of a License, Permit, or Certificate

- 1. The Chief Health Officer or his/her designee may suspend or revoke a license, permit, or certificate if the license holder:
 - a. Violates this Chapter or ARS 36-601, or
 - b. Provides false information on a license application.
- 2. If the regulatory authority finds that conditions in a licensed or permitted facility are a severe and imminent health hazard as to require emergency action, and incorporates a finding in its order, summary suspension of the facility's license or permit may be ordered pending proceedings for

revocation or other action. Upon suspension pursuant to this Section, the holder of the license or permit or certificate may–request to vacate the suspension order, and the Chief Health Officer or his/her designee shall hold an Informal Administrative Hearing within five (5) days. In no event,

may a summary suspension order remain in effect for more than twenty-five (25) days.

- 3. After providing opportunity for hearing, the regulatory authority may revoke a license, permit, or certification for serious or repeated violations of any of the requirements of this Chapter or for interfering with the regulatory authority's performance of duty.
- 4. Prior to revocation, the regulatory authority shall notify the holder of the license, permit, certification, or the person in charge, the specific reasons for which the license, permit, or certification shall be revoked at the end of the twenty (20) days following service of a written notice. The revocation becomes final unless a written request for a hearing is filed with the regulatory authority. If a request for a hearing is timely filed, the hearing shall be held within twenty (20) days of receipt of the request.
- F. Services of Notices A notice provided in this Section of the Chapter is properly served when it is delivered to the holder of the license, permit, certification, or person in charge, or when it is sent by registered or certified mail, return receipt requested, to the last known address of the license holder or permit. A copy of the notice shall be filed in the records of the regulatory authority. The notice shall comply with the provisions of ARS 41-1092.
- G. Hearings held pursuant to the provisions of this Chapter shall be conducted in accordance with the requirements of Arizona Revised Statute 41-1092.
- H. Appeal to the Board of Directors
 - 1. Any party may appeal to the Board of Directors the final finding and/or sanction of the Hearing Officer. A written notice of appeal shall be filed with the Hearing Officer within ten (10) days after the findings.
 - 2. The notice of appeal shall identify the finding and/or sanction appealed. It shall be signed by the appellant or appellant's counsel, and shall contain the names, addresses, and telephone numbers of all parties and their attorneys. When a party appeals, the Chief Health Officer or Hearing Officer shall send a copy of the notice of appeal to the other party or attorney.
 - 3. Appeals shall be limited to the record of the proceeding before the Hearing Officer, and no new evidence may be introduced. The record of the proceedings shall include all materials in the Chief Health Officer's or Hearing Officer's file, all evidence admitted at the hearing, and the official record as per this Code.
 - 4. Upon receiving the notice of appeal the regulatory authority shall within thirty (30) days prepare and transmit the record and schedule the appeal before the Board of Directors.
 - 5. The parties may stipulate that the appeal may be heard on less than a complete record or upon stipulated facts. The designation of the stipulated record shall be in writing and filed with the Hearing Officer within fifteen (15) days after the notice

of appeal.

6. Upon sending the record to the Board of Directors, the regulatory authority shall notify the parties that they have five (5) days from the date of the letter to submit a memorandum stating the parties' position to be submitted at the Board of

Directors' hearing.

- 7. The memoranda shall be submitted to the Clerk of the Board and shall not exceed five (5) pages in length.
- 8. A notice of appeal before the Board of Directors shall be posted at least twenty-four (24) hours prior to the hearing. The regulatory authority shall mail a notice of the hearing to both parties not less than five (5) days prior to the meeting.
- 9. The Chairman of the Board of Directors shall preside at the appeal and shall decide on all questions pertaining to the procedure. Final decisions on the merits of the case shall be made upon motion and majority vote of the quorum.
- 10. At the Board of Directors' hearing, arguments on appeal shall be limited to five(5) minutes for each party unless extended by the Chairman of the Board of Directors.
- 11. After consideration of the merits of an appeal, the Board of Directors may increase, decrease, or modify any sanction imposed by the Hearing Officer and may:
- a. Affirm the action of the Hearing Officer;
- b. Reverse the action of the Hearing Officer and, if necessary, remand for further proceedings.
- c. A decision to reverse the action of the Hearing Officer in whole or in part must be based upon a finding of an abuse of discretion by the Hearing Officer.
- I. Appeal of a Decision of the Board of Directors An appeal of the decision of the Board of Supervisor may be made by filing a complaint in the Coconino County Superior Court within thirty (30) days of the Board's decision, pursuant to A.R.S. Title 12 Chapter 7 Article 6 (ARS 12-901 et seq.).
- J. Application after Revocation Whenever a revocation of a license, permit, or certificate has become final, the holder of the revoked license, permit or certificate may make written application of a new license, permit, or certificate following a 90 day waiting period. The holder of the revoked license is responsible for all plan review and preopening requirements and shall pay the fee for the cost of providing a Hearing Officer for the revocation hearing.

APPENDIX A

UNIVERSAL PRECAUTIONS

The UNIVERSAL PRECAUTIONS, published by the Centers for Disease Control (CDC), are a set of guidelines which health workers (including PSWs) should employ consistently with all patients/clients, in order to prevent parenteral, mucous membrane, and nonintact skin exposure to bloodborne pathogens.

The following Universal Precautions have been abstracted for their specific relevance to PSWs.

1. Needlestick injuries

Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices: a) when handling sharp instruments after procedures; b) when cleaning used instruments; c) when disposing of used needles.

Do not recap used needles by hand; do not bend, break, or otherwise manipulate used needles by hand.

Place used needles and other sharp items in puncture-resistant containers for disposal. Locate these containers as close to the use area as is practical.

Flagst	aff.	AZ.
I Iuzsi	uıı.	<i>1</i> 12.

NAU Mountain Campus Employee Occupational Exposure Procedure				
Initial	1. Remove soiled clothing and wash exposed area with soap and water, if			
Response	appropriate.			
	2. Administer first aid as appropriate to the exposure.			
Immediate	1. Immediately notify attending physician/supervisor of exposure.			
Reporting &	2. Employee shall present at the NAU Health Center, ER, or Urgent Care for			
Medical	assessment and initial prophylactic treatment, if applicable. If employee goes to a			
Evaluation	private physician, download the Workers Compensation Physician Information			
	Sheet from http://hr.nau.edu/sites/default/files/files/workers_comp_info_sheet.doc			
	3. Employee should present this CARD to treating health care provider.			
Documentation	1. Following the incident, the supervisor must report all employee-related injuries			
& Follow-Up	by:			
	I. Fill out the Supervisor's Report of Injury Form (SRI) and send to NAU HR			
	II. Call State of Arizona, Workers' Compensation Early Claims Reporting			
	Services at 1-800-837-8583 prior to the end of the shift on the day of the			
	occurrence.			
	2. For Blood/Body Fluid Exposures: Following the incident, the health care provider			
	shall immediately make available to the affected employee a copy of all the			
	employee's records relating the treatment and follow up, and if and when			
	available, results regarding the HIV, HBV, and HCV status of the source, to the			
	extent permitted by the law.			

2. Gloves and other protective barriers

Use protective barriers to prevent exposure to blood, body fluids containing visible blood, and other fluids to which Universal Precautions apply. The types of protective barriers used should be appropriate for the procedures being performed and the type of exposure anticipated.

3. Hand washing

Immediately and thoroughly wash hands and other skin surfaces that are contaminated with blood, body fluids containing visible blood, or other body fluids to which Universal Precautions apply.

4. Health problems

Health Care Workers who have weeping dermatitis or draining lesions should refrain from all direct patient/client care and from handling patient-care equipment until the condition has cleared.

5. Pregnancy

Pregnant health care workers are not known to be at greater risk of contracting HIV infection than non-pregnant health care workers. However, they should be especially familiar with, and strictly adhere to, precautions to minimize this risk.

Excerpted from, "CDC. Update: Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in health-care settings". Morbidity and Mortality Weekly Report, June 24, 1998; 37(24):377-378.



PUBLIC NOTICE Body Art Disclosure Statement

Must be posted in a conspicuous location

Tattooing, permanent make-up, piercing and other forms of body art may involve possible health risks. Body art could result in:

1. Pain, bleeding, swelling, infection, scarring of the pierced area, nerve damage, and/or transmission of communicable diseases such as Hepatitis B & C, HIV/AIDS, etc.

The Health District encourages potential body art recipients to educate themselves of the risks associated with body art. Take time to discuss body art procedures and sanitation with the operator.

The body art operator must:

- 1. Clean and disinfect the body art procedure area.
- 2. Clean the area on the body that will receive body art.
- 3. Use needles only one time. Ink for tattoos should be dispensed into an ink cap and must be disposed of after body art procedure is finished. Corks, rubber bands, etc. should be cleaned and used only once. Common supplies must be dispensed in a manner that prevents cross-contamination.
- 4. Use sterilized equipment when performing procedures. Look for sealed & sterilized peel packs.
- 5. Have an approved sharps container for needle or sharps disposal.
- 6. Wash hands before procedure(s), at any time hands become contaminated, and after removing gloves.
- 7. Wear clean disposable single-use gloves that should be changed with each new customer, before and after clean-up and set-up, and as often as necessary during a procedure to prevent cross-contamination.
- 8. Talk to the body art recipient about proper aftercare of tattoo, piercing, and permanent make-up.
- 9. Practice "clean" technique to prevent cross-contamination.
- 10. Have a current body art operator health card and current blood-borne pathogen training.

If you have questions, please contact the Coconino County Public Health Services District at 928.679.8760 2500 N Fort Valley Road Bldg #1 Flagstaff, AZ 86001

APPENDIX C

Center for the Disease Control and Prevention Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008

The Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, presents evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of patient-care medical devices and for cleaning and disinfecting the healthcare environment. The entire guidelines can be found on the website: http://www.cdc.gov/hicpac/Disinfection_Sterilization/13_11sterilizingPractices.html

The following Universal Precautions have been abstracted for their specific relevance to event-related shelf-life:

Sterilizing Practices

Overview. The delivery of sterile products for use in patient care depends not only on the effectiveness of the sterilization process but also on the unit design, decontamination, disassembling and packaging of the device, loading the sterilizer, monitoring, sterilant quality and quantity, and the appropriateness of the cycle for the load contents, and other aspects of device reprocessing. Healthcare personnel should perform most cleaning, disinfecting, and sterilizing of patient-care supplies in a central processing department in order to more easily control quality. The aim of central processing is the orderly processing of medical and surgical instruments to protect patients from infections while minimizing risks to staff and preserving the value of the items being reprocessed⁹⁵⁷. Healthcare facilities should promote the same level of efficiency and safety in the preparation of supplies in other areas (e.g., operating room, respiratory therapy) as is practiced in central processing.

Ensuring consistency of sterilization practices requires a comprehensive program that ensures operator competence and proper methods of cleaning and wrapping instruments, loading the sterilizer, operating the sterilizer, and monitoring of the entire process. Furthermore, care must be consistent from an infection prevention standpoint in all patient-care settings, such as hospital and outpatient facilities.

Storage. Studies in the early 1970s suggested that wrapped surgical trays remained sterile for varying periods depending on the type of material used to wrap the trays. Safe storage times for sterile packs vary with the porosity of the wrapper and storage conditions (e.g., open versus closed cabinets). Heat-sealed, plastic peel-down pouches and wrapped packs sealed in 3-mil (3/1000 inch) polyethylene overwrap have been reported to be sterile for as long as 9 months after sterilization. The 3-mil polyethylene is applied after sterilization to extend the shelf life for infrequently used items ⁹⁶⁷. Supplies wrapped in double-thickness muslin comprising four layers, or equivalent, remain sterile for at least 30 days. Any item that has been sterilized should not be used after the expiration date has been exceeded or if the sterilized package is wet, torn, or punctured.

Although some hospitals continue to date every sterilized product and use the time-related shelf-life practice, many hospitals have switched to an event-related shelf-life practice. This latter practice recognizes that the product should remain sterile until some event causes the item to become contaminated (e.g., tear in packaging, packaging becomes wet, seal is broken)⁹⁶⁸. Event-

related factors that contribute to the contamination of a product include bio burden (i.e., the amount of contamination in the environment), air movement, traffic, location, humidity, insects, vermin, flooding, storage area space, open/closed shelving, temperature, and the properties of the wrap material ^{966, 969}. There are data that support the event-related shelf-life practice ⁹⁷⁰⁻⁹⁷². One study examined the effect of time on the sterile integrity of paper envelopes, peel pouches, and nylon sleeves. The most important finding was the absence of a trend toward an increased rate of contamination over time for any pack when placed in covered storage ⁹⁷¹. Another evaluated the effectiveness of event-related outdating by microbiologically testing sterilized items. During the 2-year study period, all of the items tested were sterile ⁹⁷². Thus, contamination of a sterile item is event-related and the probability of contamination increases with increased handling ⁹⁷³.

Following the sterilization process, medical and surgical devices must be handled using aseptic technique in order to prevent contamination. Sterile supplies should be stored far enough from the floor (8 to 10 inches), the ceiling (5 inches unless near a sprinkler head [18 inches from sprinkler head]), and the outside walls (2 inches) to allow for adequate air circulation, ease of cleaning, and compliance with local fire ordinances (e.g., supplies must be at least 18 inches from sprinkler heads). Medical and surgical supplies should not be stored under sinks or in other locations where they can become wet. Sterile items that become wet are considered contaminated because moisture brings with it microorganisms from the air and surfaces. Closed or covered cabinets are ideal but open shelving may be used for storage. Any package that has fallen or been dropped on the floor must be inspected for damage to the packaging and contents (if the items are breakable). If the package is heat-sealed in impervious plastic and the seal is still intact, the package should be considered not contaminated. If undamaged, items packaged in plastic need not be reprocessed.